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Research Article

Can the Hazard Assessment and Critical Control Points (HACCP) system be used to design process-based hygiene concepts?

Kann das Hazard Assessment and Critical Control Points (HACCP)-System Grundlage für prozess-basierte Krankenhaushygienekonzepte sein?

Abstract

Recently, the HACCP (Hazard Analysis and Critical Control Points) concept was proposed as possible way to implement process-based hygiene concepts in clinical practice, but the extent to which this food safety concept can be transferred into the health care setting is unclear. We therefore discuss possible ways for a translation of the principles of the HACCP for health care settings. While a direct implementation of food processing concepts into health care is not very likely to be feasible and will probably not readily yield the intended results, the underlying principles of process-orientation, in-process safety control and hazard analysis based counter measures are transferable to clinical settings. In model projects the proposed concepts should be implemented, monitored, and evaluated under real world conditions.

Zusammenfassung

Das HACCP-Konzept (Hazard Analysis and Critical Control Points)-Konzept ist in jüngerer Zeit wiederholt als Möglichkeit für prozess-basierte Hygienekonzepte vorgeschlagen worden. Wie aber dieses, aus der Lebensmittelsicherheit stammende Konzept in der Gesundheitsfürsorge tatsächlich realisiert werden kann, ist unklar. Deshalb prüften wir Möglichkeiten einer Übertragung der Grundsätze des HACCP auf Anforderungen der Gesundheitsversorgung am Beispiel des Managements multiresistenter Erreger. Während eine direkte, unreflektierte Umsetzung der Lebensmittelkonzepte in die Gesundheitsversorgung weder machbar ist noch zu den gewünschten Ergebnissen führt, können die Grundprinzipien Prozessorientierung, Qualitätssicherung und Gefahrenanalysen-basierte Gegenmaßnahmen auch in der medizinischen Versorgung zur Anwendung kommen. In Modellimplementierungen sollten die vorgeschlagenen Konzepte unter realen Bedingungen erprobt, evaluiert und bewertet werden.

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Introduction

The recent amendments to the federal regulations for infection control in Germany (Infektionsschutzänderungsgesetz, 2011) have renewed the call for patient safety and high hygienic standards in health care facilities [1]. Conventionally, in-house directives for hygiene are based on regulations or guidelines and recorded in manuals. The primary principle of order in these, sometimes quite extensive, documents is in most cases the institutional organisation structure of a hospital (departments, wards, and so on). This concept pays little or no attention to the individual patient or his or her personal path through the hospital and – more generally – through the health care system. Quality control is based on spot-checks of structure parameters by internal and external auditors as well as monitoring of outcome parameters (infection) in one or more substructures or patient groups by application of some of kind surveillance system ideally linked to the clinical information system (KISS, Krankenhaus-Infektions-Surveillance-System) (Figure 1). It has been estimated that well-planned directives based on this approach in combination with good compliance and close surveillance are able to reduce hospital acquired infections by up to 30% compared to control [2], [3].

Infection control specialists have repeatedly demanded a general change of the underlying philosophy in hospital hygiene away from a static, method based to a dynamic,

process-oriented infection prevention management system. Some have proposed a conception based on the Hazard Analysis and Critical Control Points (HACCP) concept, but little has been published addressing the actual realisation of this food safety concept into health care settings so far [4].

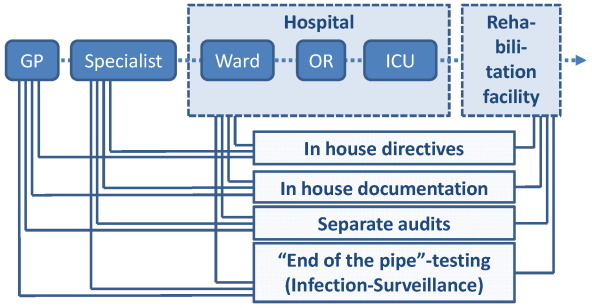

Figure 1: The classic approach in hospital hygiene: Individual health care providers (HCPs) have individual in-house directives and documentation. Quality assurance relays on audits (internal and external by different authorities) and spot checks of outcome quality by infection surveillance. The treatment process as such is somewhat detached from this scheme.

The HACCP concept was developed back in the 1960s by the NASA (National Aeronautics and Space Administration), the Pillsbury Company and the U.S. Army Laboratories at Natick as reaction to the requirements for save foods for space flights. Primarily used in food processing only, its potential was soon realized and it is now widely used in food and pharmaceutical processes from primary production to processing, distribution and consummation. It was endorsed by the Codex Alimentarius Commission as the most cost-effective way devised to date for ensuring the safety of food in 1993 [5], [6]. The underlying idea is to integrate safety control into the design of the process rather than resort to end-product testing which has been shown to be highly ineffective [5]. The HACCP consists of few, rather simple principles (Figure 2) [7].

The process has to be broken down into logical steps and possible hazards have to be identified for every step and the whole process. At certain points, monitoring and regulative steps (so called Critical Control Points, CCPs) are integrated into the process. CCPs are designed to regulate in a way that a hazard can be prevented, eliminated or reduced to acceptable levels (in food safety that could be cooking, acidification or drying for example). Monitoring steps ensure the transparency of the process and allow control as well as taking counter measures or corrective action (an additional CCP, for example) wherever, and whenever necessary. The power of CCPs (= the ability of CCPs to reduce risks in the process) as well as the frequency and type of monitoring (structure-, process- and outcome-parameters) must be characterized. The HACCP plan as well as the process must be documented and validated [5]. The HACCP offers a scientific, rational and systematic approach for identification, assessment and reduction of hazards during production, processing, manufacturing, preparation and use of food and is one of the most successful quality management concepts worldwide.

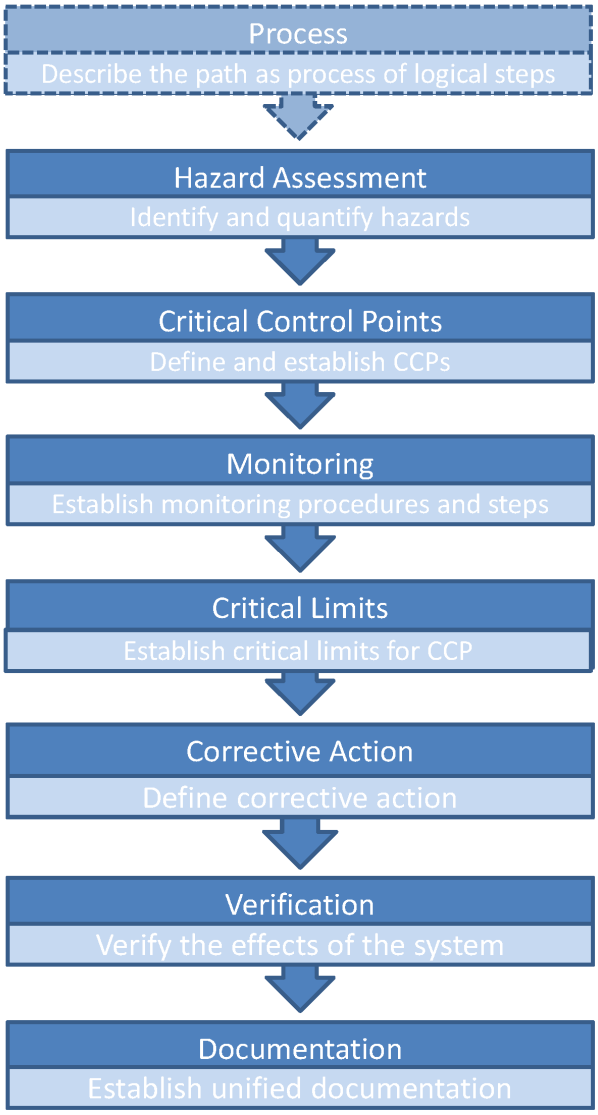

Figure 2: The Principles of the HACCP. Process-orientation is assumed beforehand. The order of "Corrective action" and "Monitoring" were swapped for didactic reasons. [7]

As a direct implementation of food processing concepts into health care is not very likely to be feasible or yield the intended results, an extraction of the underlying philosophy and careful adaptation to the specific needs in health care settings seems to be needed. We therefore worked out possible ways for a translation of the principles of the HACCP into health care settings.

Method

After adopting a process oriented point of view of the paths of patients through the health care system, we tried to identify possible ways to translate the HACCP concepts into a variety of clinical settings. An adaptation of the HACCP for clinical settings was designed and specifically formulated. As example the management of multi-resist-

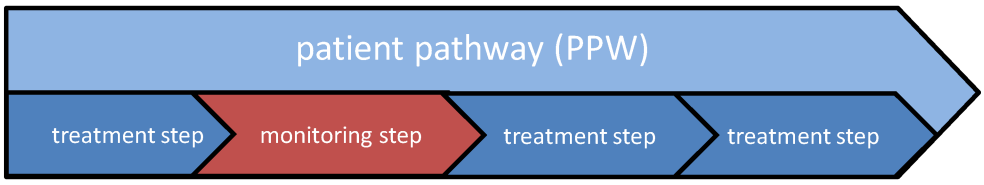

Figure 3: Scheme of the flow of the patient (patient pathway, PPW) through the health care system. Multiple steps and different HCPs form a "treatment chain"

ant organisms (MRO) was used to evaluate how the seven HACCP principles: hazard analysis, identification of critical control points, establishment of critical limits, description of corrective action, monitoring, documentation and verification can be adopted to clinical situations.

Results

Medical treatment from a process-orientated point of view

The flow of the patient trough the health care system with its multitude of heterogenous procedures can be defined as a pathway (patient pathway, PPW) or as production process with the targeted outcome of improving or restoring the patient's health. Under this perspective, the patient and his PPW become the primary method of order, to which all hygienic measures have to be linked to. Normally, a PPW is not limited to one health care provider (HCP) but involves multiple steps and HCPs. In this process, additional steps for monitoring and regulation can be included (Figure 3).
The logic steps that form this process can be easily defined. They occur as natural marks every time when either the patient is referred to another subunit within one HCP or to another HCP (process-defined mark) or if the health of the patient significantly changes or will change (patient-defined mark) (Table 1).

Table 1: Typical examples for process- and patient-defined marks in the PPW

Process-defined marks	Patient-defined marks
▪ Referral to another HCP	▪ Significant changes of the immunity
▪ Admission and discharge	▪ Begin or end of intensive care
▪ Before an operation	▪ Infection with unclear pathogen

For every single step, a hazard analysis can be performed and monitored as well as regulative steps can be included. As the PPW is normally planed beforehand, future changes that will affect the hazard analysis in the next steps (e.g. upcoming operation or immunosuppression) can be included into the actual management, allowing the integration of certain regulative steps as pro-active counter measures.

Proposed adaptation of the HACCP principles for healthcare settings

Key element of the adaptation is a process-orientated perspective (Figure 1). Patients with similar symptoms or diagnosis often have closely related clinical paths. Moreover, HCPs tend more and more to standardise clinical pathways providing grounds to integrate hygienic measures based on the HACCP principles.

Hazard analysis

For every single step or sub-process within a clinical pathway, a hazard analysis has to be performed. In contrast to food safety, both the hazard for the patient, and the hazard associated with the patient have to be taken into account: The risk the patient is at (e.g. by a certain procedure or condition or to acquire an infection) as well the risk the patient poses to other patients, health care workers, or visitors (e.g. to transmit a MRO to them) have to be assessed.
In the context of MROs, a hazard analysis needs to differentiate "risk patients" into patients who have a high risk to transmit MROs to others (better referred to as "endangering patients") and patients who have a high risk to acquire MROs or contract an infection ("endangered patients").
The hazard posed by "endangering patients" to transmit MROs to others in each step can be simplified as follows

$$H_t = c \cdot n \cdot p$$

with
H_t = hazard of transmission of an MRO
c = probability to be carrier of an MRO
n = number of opportunities for a transmission
p = probability of a transmission for each opportunity
For different organisms, different ways of transmission (e.g. hands/HCWs, surfaces, water, air) have been described

$$n \cdot p = \sum_{i=h,s,a,x} (n_i \cdot p_i) = n_h \cdot p_h + n_s \cdot p_s + n_a \cdot p_a + n_x \cdot p_x$$

with
n_h = number of opportunities for transmissions by hands
p_h = probability of transmission by hands for each opportunity

n_s = number of opportunities for transmissions by surfaces
p_s = probability of transmission by surfaces for each opportunity
n_a = number of opportunities for transmissions by air
p_a = probability of transmission by air for each opportunity
n_x = number of opportunities for transmissions by other means
p_x = probability of transmission by other means for each opportunity
resulting in

$$H_t = c \cdot \sum_{i = h,s,a,x} (n_i \cdot p_i)$$

The probability to be carrier of an MRO is associated with certain "risk factors" and/or microbiological results indicating colonisation or infection. The probability of transmission is determined by the organism, the density and location of colonisation/infection and other factors (compliance with hygienic measures, antimicrobial therapy). The number of opportunities is designated by the clinical setting (outpatient, in-patient, intensive care).
Likewise, the hazard the "endangered patient" is exposed to every step can be described as

$$H_r = (1 - c) \cdot (n \cdot p + H_d)$$

respectively

$$H_r = (1 - c) \cdot \left(\sum_{i = h,s,a,x} (n_i \cdot p_i) + H_d \right)$$

with
H_r = hazard of receiving a MRO
$(1 - c)$ = probability to be no carrier of a MRO
H_d = hazard of development of a de-novo-resistance, in which

$$H_d = n_d \cdot p_d$$

with
n_d = number of opportunities for development of a de-novo-resistance
p_d = probability of development of a de-novo-resistance
The probability to be no carrier of MRO is associated with the absence of "risk factors" and/or microbiological results. Probabilities of carriage and non-carriage sum up to 1. The probability of transmission is related to the susceptibility of the "endangered patient" (for example the presence of open wounds, immunosuppression, antibiosis). The number of opportunities is designated by the clinical setting (outpatient, in-patient, intensive care). The opportunity and probability of de-novo-resistances is associated with the frequency, type and application of antibiosis.
The hazard of a transmission from a carrier to a susceptible receptor therefore depends not only on the hazard associated with the carrier, but with possible receptors, too. For every step, this can be expressed as

$$H = H_t + H_r$$

The global hazard of transmission for the whole process depends on the number of steps in the clinical pathway and the respective hazard associated with every step. Still, the exact relation is much more complex to describe, because the probability of transmission depends not only on the factors associated with each step, but also depends on a possible transmission in the preceding steps. A Marcov model could be used to describe this phenomenon but this would be beyond the scope of this article. For the resulting health risk associated with a particular MRO, the pathogenicity of the organism and the immunity of the patient have to be considered, too.

Monitoring steps

Monitoring steps include checks of the structure-, process- and outcome-parameters in the PPW. For MROs this could include assessing the individual risk of a patient to endanger or be endangered by MROs by soliciting his or her risk factors (e.g. structure: health status; process: treated in other hospitals with known problems with MROs, recent antibiosis; outcome: microbiological sampling). These steps can be included into the process on defined marks (see above) e.g. by admittance to a hospital [8], [9] before an operation [10] and/or after decolonisation [11].

Regulative steps

Regulative steps are included into the PPW to reduce a hazard. This includes adaptation of antibiosis when a certain resistance is suspected, isolation measures (of possible of both donors and recipients) based on the risk assessment, reducing the probability of transmission, and decolonisation treatments [8].

Corrective action

If results from monitoring indicate, that the process is out of control, e.g. an outbreak of MROs is detected; corrective actions tailored to the severity of the loss of control have to be undertaken. This could start with extra training of the HCWs and patients and additional screening of contacts and escalate up to closing wards.

Documentation

The PPW, results of the hazard analysis, monitoring and regulative steps, and corrective action must be documented and available to all HCWs involved. Uniform structured documents should be used to record individual data (e.g. results from monitoring steps) and must be forwarded to all HCPs down the process line.

Verification

Verification and validation are integral parts of the HACCP. In the context of MROs, documentation of structure- and process parameters, regular internal and external audits, check in/check out surveys [12], surveillance of infections caused by MROs and random sampling of a proportion of patients to identify occult transmissions are possible ways to show the effectiveness of the system.

Discussion

Conventional hospital infection prevention concepts have been shown to be effective in reducing nosocomial infection down to a certain incidence. However, despite all efforts, infection rates and antibiotic resistance rates in Germany are still at levels that raise severe concerns [3], [13], [14]. Health care settings on the other hand have changed dramatically under the pressures associated with the G-DRG-system and numerous approaches to improve competitiveness of HCPs. Therefore, new concepts to realise hygienic safety are needed. We have tried to analyse whether and how process-orientated infection prevention can be based on principles of the HACCP-concept.

Our idea is based on the three columns: process-orientation, continuous quality-assurance in all steps and subprocesses and introduction of CCPs and monitoring points into the process based on a comprehensive hazard analysis.

Adapting a process-orientated perspective is the key element for this approach. While every patient is an individual and has his or her very own medical history, patients with similar symptoms or diagnosis usually have more or closely related clinical paths. Moreover, as HCPs tend more and more to standardise clinical pathways, they also lay the grounds for the implementation of a process-based infection prevention concept.

As all steps in the treatment process should contribute to the goal, the same level of hygienic safety has to be warranted throughout the process as well. This, on the other hand, implies that standards or measures are not the same throughout the process of one patient or for all patients of one HCP. That is a fundamental difference to the conventional approach that basically tries to establish the same standard for all patients on one clinical unit (ward e.g.). Understanding the PPW as inter-institutional and cross-sectoral process necessarily means that the infection control directives of different HCPs in the PPW be harmonized and made transparent (Figure 4). This can help HCWs employed by different HCPs to see themselves as part of a PPW rather than as isolated units and therefore may enhance the system-wide security culture.

This has been successfully achieved by regional networks and quality circles which were monitored by independent external audits [15], [16], [17], [18].

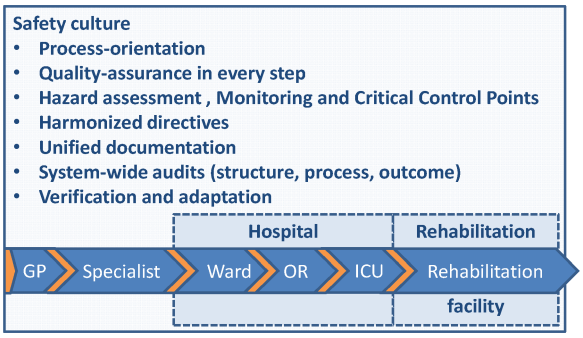

Figure 4: The proposed alternative system based on HACCP principles

Our manuscript has several limitations. Firstly, as we have assessed the possible way to use the concepts of the HACCP in the clinical setting, other ways to implement process-orientated hygiene that are easier or more effective may exist. Second, as the proposed concept is in some points quite different to the conventional perspective, it is unclear what marginal conditions have to be met for a successful implementation. Moreover, the exact values of the variables for the hazards assessment as well as the actual power of CCPs are largely unknown and may not be completely quantifiable. Still, this is a problem known in food hygiene and more or less true for all infection control concepts. As workaround, unknown values can be estimated based on literature evidence, guidelines and expert opinion for particular clinical units [19]. Third, as the concept is new, no real world data on the actual extra benefit of this concept (if fully and successfully implemented) is available yet, rendering our considerations preliminary.

The proposed change from a static, structure-orientated perspective to a dynamic process-orientated one does not necessarily mean that everything has to be changed or newly invented. For example, the HACCP concept has already been successfully adapted for water safety in hospitals, helping to prevent water-associated infections [20], [21]. Actually, many clinical pathways and hygienic directives use the principles of the proposed modified HACCP but without specifically addressing this [12], [22], [23]. Seeing these successful and well accepted measures from a new perspective could not only help to understand why some interventions work and others not, but also help to improve the concepts in general and overcome certain controversies in infection prevention. The main idea of the HACCP to integrate safety control into the design of the process rather than maintaining a rather ineffective “end-product testing” as spot-checks of the results (e.g. infection or not) has the potential to change current hospital hygiene in an innovative, sustainable, forward-looking way. Further research should evaluate the proposed concepts under real world conditions.

Conclusion

The HACCP can be used to design process-based clinical hygiene concepts. The underlying principles of process-orientation, in-process safety control and hazard analysis based counter measures can be transferred into clinical settings. This translational approach could help infection prevention to better cope with the infectious challenges of modern health care.

Notes

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Competing interests

The authors declare that they have no competing interests.

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